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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES of AMERICA v. THOMAS M. RODGERS, JR., Defendant.	CRIMINAL NUMBER: 00-10118 21 U.S.C. §§331(p) and 333(a)(1) (Food Drug & Cosmetic Act, Unregistered Manufacture) (1 count) 21 U.S.C. §§331(d) and 333(a)(1) (Food Drug & Cosmetic Act, Shipment of Unapproved New Drug) (1 count) 21 U.S.C. §§331(a) and 333(a)(1) (Food Drug & Cosmetic Act, Shipment of Adulterated Drug) (1 count)

INFORMATION

The United States Attorney Charges:

Allegations Common to All Counts

1. At times material to this Information, defendant THOMAS M. RODGERS, JR. ("RODGERS") was an individual who resided in Atlanta, Georgia.

2. At times material to this Information, Private Biologicals Corporation ("PBC")was a Delaware corporation that was registered to conduct business activities in the Commonwealth of Massachusetts.

3. At times material to this Information, Private Biologicals Corporation maintained a place of business at 10T Roessler Road, Woburn, Massachusetts.

4. At times material to this Information, PBC was in the business of producing a product called LK-200, a drug which PBC and its agents intended to be used in the treatment of a variety of diseases, including various forms of cancer.

1

5. At times material to this Information, RODGERS was Chairman of the Board of Directors and majority shareholder of PBC and, in that capacity, had a duty to ensure that PBC and its agents complied with the Federal Food Drug and Cosmetic Act and the regulations of the Food and Drug Administration.

COUNT ONE

FEDERAL FOOD DRUG AND COSMETIC ACT
(21 U.S.C. §§331(p) and 333(a)(1))
(Unregistered Drug Manufacturing)

6. The United States Attorney incorporates by reference paragraphs 1-5 of this Information, and further charges that:

7. Beginning in or about August 1993 and continuing until in or about April 1995, in Woburn in the District of Massachusetts and elsewhere

THOMAS M. RODGERS, JR.,

defendant herein, owned and caused to be operated an establishment engaged in the manufacture and preparation of drugs, to wit, a facility used for the manufacture of a substance identified as "LK-200," without registering such establishment with the Secretary of Health and Human Services in violation of Title 21, United States Code, Sections 331(p) and 333(a)(1) and Title 18, United States Code, Section 2.

COUNT TWO

FEDERAL FOOD DRUG AND COSMETIC ACT
(21 U.S.C. §§331(d) and 333(a)(1))
(Shipment of Unapproved New Drug)

8. The United States Attorney incorporates by reference paragraphs 1-5 of this Information, and further charges that:

9. Beginning in or about August 1993 and continuing until in or about April 1995, in Woburn in the District of Massachusetts and elsewhere

THOMAS M. RODGERS, JR.,

defendant herein, caused to be introduced and delivered for introduction into Interstate Commerce a new drug, to wit, a substance identified as "LK-200," without an application approved by the Secretary of Health and Human Services, in violation of Title 21, United States Code, Sections 331(d) and 333(a)(1) and Title 18, United States Code, Section 2.

COUNT THREE

FEDERAL FOOD DRUG AND COSMETIC ACT
(21 U.S.C. §§331(a) and 333(a)(1))
(Shipment of Adulterated Drug)

10. The United States Attorney incorporates by reference paragraphs 1-5 of this Information, and further charges that:

11. Beginning in or about August 1993 and continuing until in or about April, 1995, in Woburn in the District of Massachusetts and elsewhere

THOMAS M. RODGERS, JR.,

defendant herein, caused to be introduced and delivered for introduction into Interstate Commerce a drug, to wit, a substance identified as "LK-200," that was adulterated in that it was prepared, packed and held under insanitary conditions whereby it may have been contaminated and in that the methods used and the facilities and controls used for its manufacture, processing, packing and holding did not conform with Current Good Manufacturing Practice to assure that it met the requirements of the Food Drug and Cosmetic Act as to safety and that it had the identity, strength and quality it was represented to possess, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1) and Title 18, United States Code, Section 2.

dated:

DONALD K. STERN
United States Attorney

By: 

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